

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS
LIABILITY LITIGATION**

MDL No. 2419

Dkt. No. 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

All Cases Against the Specialty Surgery Center Defendants

**PLAINTIFFS' STEERING COMMITTEE'S REPLY IN SUPPORT OF
MOTION FOR JUDGMENT ON THE PLEADINGS REGARDING COMPARATIVE
FAULT DEFENSES ATTRIBUTING FAULT TO GOVERNMENTAL
ENTITIES [DKT. NO. 3249]**

The Plaintiffs’ Steering Committee respectfully submits this Reply in support of its Motion for Judgment on the Pleadings [Dkt. No. 3249]. In their opposition brief and associated joinder (Dkt. Nos. 3278 (SSC Defendants) and 3279 (joinder by Calisher & Associates) (collectively, the “Defendants”)) the Defendants do not offer a single example in the entirety of American jurisprudence where a governmental entity has been apportioned comparative fault in a case on the basis that such governmental entity failed to timely prevent a harm from occurring to a plaintiff. In other words, Defendants’ comparative fault defense against the Non-Party Governmental Entities appears to be unprecedented in American law. The Court should decline to extend the doctrine of comparative fault in this instance, as it would simply be a gross injustice to the victims of this national tragedy.

I. The Defendants Concede that the Tennessee Doctrine of Comparative Fault Requires Them to Prove a *Prima Facie* Case of Negligence Against Each Governmental Entity, Including the Duty Element

As they must, the Defendants concede (or at least do not dispute) the following crucial points asserted in the PSC's original brief concerning the Tennessee doctrine of comparative fault:

- (1) The Defendants must state a *prima facie* case of negligence against any non-party that they contend was comparatively negligent;¹
- (2) A *prima facie* case of negligence requires the existence of a duty;²
- (3) Only after a duty is established does comparative fault come into play;³ and
- (4) A duty to the public at large is a duty owed to no one.⁴

They also admit that, in light of the public duty doctrine, no one can recover from any of the Non-Party Governmental Entities absent a showing that a particular entity owed a “special duty” to a Plaintiff.⁵ Although the Defendants contend that the FDA and the MBOP owed a “special duty” to the Plaintiffs, they do not purport to claim that the TDOH or the TBOP owed a duty to a Plaintiff.

II. Because The Non-Party Governmental Entities Owed No Duty to any of the Plaintiffs, the Defendants Cannot Establish the Requisite *Prima Facie* Case of Negligence Against Those Entities.⁶

The Defendants *do not identify a single case* – in Tennessee or otherwise – in which a court has held that a government entity’s “duty to the public” can satisfy the duty element for purposes of comparative fault. That is not surprising, because a holding to that effect would be manifestly unjust and would contravene the essence of the public duty doctrine, which is that governmental entities by default *owe no duty* to particular plaintiffs. Moreover, the Defendants

¹ See Dkt. No. 3278 at pp. 4-5 (citing *Free v. Carnesale*, 110 F.3d 1227, 1231 (6th Cir. 1997)).

² The parties differ as to what is required to meet this element; the Defendants contend that a “duty to the public” is sufficient (Dkt. No. 3278 at p. 4), even though a duty to the public is insufficient to establish negligence by a government actor.

³ *Coln v. City of Savannah*, 966 S.W.2d 34, 42 (Tenn. 1998); *Blair v. Campbell*, 924 S.W.2d 75 (Tenn. 1996) (“[O]ur adoption of principles of comparative fault did not alter the analysis applicable to the common-law concept of duty . . .”).

⁴ *Brown v. Hamilton Cnty.*, 126 S.W.3d 43, 48 (Tenn. Ct. App. 2003).

⁵ Dkt. No. 3278 at p. 5. With respect to the FDA and the MBOP only, the Defendants contend that a “special duty” existed because of the Defendants’ allegations of recklessness by those entities.

⁶ For purposes of this section, the PSC will assume that the FDA and MBOP owed no special duty to any Plaintiff. The PSC addresses that issue separately herein.

do not provide a single case in the history of American jurisprudence in which a court has held a government agency liable to an injured plaintiff simply for failing to enforce a regulation against an entity within its jurisdiction. By the Defendants' tortured logic, Tennessee law mandates that the Non-Party Governmental Entities are not at fault for negligence, but the Defendants nevertheless can argue at the trial they were at fault. There is no reason for the Court to permit this unprecedented and perverse theory of comparative fault to proceed past the pleading stage.

The Defendants engage in a digression as to whether the public duty doctrine should be treated as an "immunity" rather than a consideration of the "duty" element of a negligence claim. Admittedly, some Tennessee decisions characterize the doctrine as an "immunity" (always in a context in which the distinction makes no difference)⁷ while others treat it as a question of establishing the duty element of a negligence claim.⁸ There is no need for the Court to cherry pick Tennessee cases here. The basic question is whether the Defendants can establish a *prima facie* case of negligence against the Non-Party Governmental Entities by showing that (1) each entity owed a duty a Plaintiff; (2) each entity breached its duty to a Plaintiff; and (3) the breach of that duty to each Plaintiff proximately caused each Plaintiff's injuries. However the public duty doctrine is characterized, it is clear that under the public duty doctrine the Non-Governmental

⁷ See, e.g., *Chase v. City of Memphis*, 1998 Tenn. LEXIS 435, at *13-14 (Tenn. July 21, 1998) (finding that the special duty exception applied where government actor affirmatively undertook to protect the plaintiff in the case). The PSC notes that the *Chase* opinion cited by the SSC Defendants (971 S.W.2d 380, 385 (Tenn. 1998)) was actually withdrawn and substituted by the aforementioned unpublished *Chase* opinion.

⁸ See, e.g., *Hurd v. Flores*, 221 S.W.3d 14, 19 (Tenn. Ct. App. 2006) (dismissing plaintiff's claims, where plaintiff failed to establish duty element in light of public duty doctrine); *Wells*, 2005 Tenn. App. LEXIS 510, at *10-15 (Tenn. Ct. App. Aug. 22, 2005) (repeatedly distinguishing between the "public duty doctrine" and "immunity," and explaining that, "[a]s in any other negligence action, a plaintiff must establish the existence of a duty or standard of care in an action for negligence of a government employee" and that "it has long been held that a plaintiff *must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general*") (emphasis added).

Entities *owed no duty* to any Plaintiff. By operation of law, governmental actors are not “negligent” simply by virtue of failing to exercise their authority relative to a person or entity within their jurisdiction. Because comparative fault incorporates the common law elements of negligence – including the duty element – the Defendants therefore cannot establish the comparative fault of the Non-Party Governmental Entities.⁹

III. The Defendants Mischaracterize the PSC’s Position and the Implications of that Position

The Defendants assert that the PSC’s position would “eliminate a defendant’s ability to assert comparative fault against the government.”¹⁰ That is not accurate. The PSC’s position is *not* that liability against an immune, governmental non-party is *per se* precluded in all conceivable circumstances. Instead, sensibly, the PSC’s position is that liability can be apportioned to a governmental non-party only where the defendant can otherwise make out a *prima facie* case of negligence against that non-party. Under that approach, there are conceivable situations in which a governmental entity could be immune from suit and yet be comparatively at fault for a plaintiff’s injuries – assuming that the element of duty is otherwise satisfied.¹¹ The situation presented here – which simply involves the allegation that a governmental entity failed to exercise its authority relative to an entity within its jurisdiction – is not one of them.¹²

⁹ See *Coln*, 966 S.W.2d at 42 (“The analysis, therefore, as in any negligence case, is first upon duty . . . *if a duty is imposed, then the surrounding circumstances are analyzed under principles of comparative fault.*”) (emphasis added).

¹⁰ Dkt. No. 3278 at p. 4.

¹¹ For example, if an employee at a county hospital allegedly committed an intentional tort by assaulting a patient, the county would retain sovereign immunity under the Tennessee Governmental Tort Liability Act, but the employee have the immune county hospital listed on the jury form for comparative fault purposes.

¹² The Defendants also suggest that the PSC’s contention is that liability cannot be apportioned to *any* immune party. That is plainly not the PSC’s position. Indeed, the PSC has not moved for judgment on the comparative fault allegations immune non-parties to this proceeding, including NECC itself (immune by virtue of its bankruptcy).

Many cases cited by the Defendants actually reinforce the PSC's premise that comparative fault can only be assigned to a governmental non-party when the government entity had a *specific duty* (rather than a duty to the public at large) and breached it. For example, in *Gregory v. Metro Gov't of Nashville*, a person sued Metro Nashville, contending that Metro Nashville 9-1-1 operators should have contacted emergency personnel in Robertson County rather than in Davidson County, and that the failure to reach out to the Robertson County emergency personnel proximately caused the decedent to experience additional pain and suffering during an ultimately fatal traffic accident.¹³ The Tennessee Supreme Court examined whether the plaintiff had established the requisite elements of a negligence claim against Metro Nashville, including the "duty of care" element.¹⁴ The Court found that Metro Nashville had *neither a statutory duty nor a common law duty* to contact the Robertson County officials, and rejected the plaintiff's argument that Metro Nashville had assumed a special duty to protect the decedent by answering a 9-1-1 call.¹⁵ Having determined that no duty existed, the court affirmed the trial's court grant of judgment on the pleadings to Metro Nashville.¹⁶

The Defendants also cite several cases applying the law of other states. As an initial matter, the law of each of the referenced states is distinct, such as in Indiana where the comparative fault regime is codified by statute. At any rate, none of the cited cases support the Defendants' stated position. In *Shand*, for example, the Indiana Court of Appeals considered whether a county highway department could be held comparatively liable for injuries suffered on

¹³ *Gregory v. Metro Gov't of Nashville*, 2012 Tenn. App. LEXIS 752, at *2-4 (Tenn. Ct. App. Oct. 26, 2012).

¹⁴ *Id.* at *14.

¹⁵ *Id.* at *14-35.

¹⁶ *Id.* at *34-35. The Court expressly did not address the application of the public doctrine. *Id.* at *35.

a road that the plaintiff alleged had been poorly maintained by the county's contractor.¹⁷ In relevant part, the court found that the county highway department in fact had a specific, non-delegable statutory duty to supervise its contractor (to whom it had delegated responsibility to construct the highway), and that the breach of that specific duty could give rise to liability for negligent supervision.¹⁸ However, the Court found no evidence that the contractor had negligently made repairs or that the county had negligently failed to supervise the maintenance.¹⁹ Here, in contrast to *Shand*, the Defendants do not identify any specific duty owed to the Plaintiffs under Tennessee statutory law or under federal law. Regardless, *Shand*'s reasoning supports the PSC's contention (consistent with Tennessee law) that comparative fault only comes into play if a defendant can show a specific legal duty to the plaintiff rather than to the public at large.²⁰

Finally, the Defendants concede that ***no court applying Tennessee law has ever permitted the allocation of comparative fault to a governmental entity that owed no duty to the plaintiff under the public duty doctrine.*** Nevertheless, they criticize the PSC for failing to discuss *Conley v. Life Care Ctrs. of Am.*, 236 S.W.3d 713 (Tenn. Ct. App. 2007). The PSC can hardly be faulted

¹⁷ *Shand Mining v. Clay Cnty. Bd. of Comm'rs*, 671 N.E.2d 477, 478-79 (Ind. Ct. App. 1996).

¹⁸ *Id.* at 481-82.

¹⁹ *Id.*

²⁰ See *Coln*, 966 S.W.2d at 42. Similarly, in *City of Vincennes v. Ruehl*, 672 N.E.2d 495, 498 (Ind. Ct. App. 1996), the same court found that an Indiana statute mandated that a city could be held liable for a contractor's injury-causing conduct, where an Indiana statute mandated that the City retain some measure of supervisory responsibility. Notably, the court observed in a footnote that if the City had been immune from liability, then attribution of fault to it would have been unwarranted. In *DeBenedetto v. CLD Consulting Engineers, Inc.*, 903 A.2d 969 (N.H. 2006), the plaintiffs did not even dispute that the New Hampshire Department Transportation was legally at fault for their injuries, and the case contains no discussion of the public duty doctrine whatsoever, let alone its application to principles of comparative fault. In *In re Air Crash Disaster at Stapleton Int'l Airport*, 720 F. Supp. 1465 (D. Colo. 1989), the court simply indicated that some governmental entities could be comparatively at fault even though the doctrine of sovereign immunity protected them from suit. None of these cases provide persuasive authority for the Defendants' positions, because the cases do not involve the application of the public duty doctrine or even a dispute as to whether the governmental entity at issue owed a duty to the plaintiff.

for omitting any reference to that case, as it sheds no light on the issues presented in the PSC's motion. There, the estate of a former nursing home resident initially brought a wrongful death action against the nursing home.²¹ After the nursing home received leave of court to amend its answer to assert the comparative fault of a psychiatric care provider and the State of Tennessee, the plaintiff added those entities as parties.²² At some point, the plaintiff apparently pursued her claim against the government separately through the Tennessee Claims Commission, which ultimately denied the claim in a separate proceeding.²³ The case proceeded to trial and the trial court (apparently after the Claims Commission had denied the plaintiff's claim against the State through the Claims Commission) permitted the nursing home to list the State of Tennessee on the verdict form for purposes of comparative fault. However, the jury ascribed 0% fault to the State and 100% fault to the nursing home.²⁴ On appeal, in relevant part, the Courts of Appeals simply found that (1) the trial court did not abuse its discretion (a lenient standard) in allowing the nursing home to amend its answer early in the case to assert comparative fault against the State of Tennessee, and (2) the issue of whether the trial court should have permitted allocation of fault to the State of Tennessee at trial was moot because the jury had apportioned 0% and therefore there was "no harm" to its inclusion on the verdict form. The *Conley* case does not even mention the public duty doctrine. Indeed, as best the PSC can discern from the opinion, the State of the Tennessee *was* potentially liable to the plaintiff for its conduct, albeit via state administrative proceedings. Most importantly, *Conley* ***expressly did not address*** the circumstances under which the allocation of fault to a governmental entity is or is not appropriate. Thus, it adds nothing to the Court's analysis here, and it certainly does not contravene the PSC's argument that the public

²¹ *Id.* at 719.

²² *Id.* at 721.

²³ *Id.* at 721.

²⁴ *Id.* at 722.

doctrine precludes the assertion of comparative fault against the Non-Party Governmental Entities.

IV. The Allegations of “Recklessness” Against the FDA and the MBOP are Insufficient to Establish the Existence of a Special Duty

Tennessee recognizes that a “special duty” can arise where a governmental actor engages in misconduct intentionally, maliciously, or recklessly.²⁵ If a special duty arises in that circumstance, the governmental entity can be held liable. Recklessness sets a high bar: the conduct must involve the “conscious disregard” of a “known risk,” constituting a “gross deviation from the standard of care.”²⁶ Importantly, an allegation that conduct was “reckless” is a legal conclusion that does not, standing alone, state a cause of action based on this “special duty” exception to the public duty doctrine.²⁷ The Defendants contend that their claims against the FDA and the MBOP should proceed because they fall within this exception to the public duty doctrine.²⁸

Notwithstanding the Defendants’ repeated characterization of the FDA’s conduct as “reckless,” the allegations do not establish *recklessness* by the FDA under the applicable legal

²⁵ *Ezell*, 902 S.W.2d at 402 (recognizing three exceptions to the public duty doctrine). The Defendants implicitly concede that they do not allege (a) any affirmative act by the Non-Party Governmental Entities to protect the Plaintiffs or (b) any state law providing a cause of action for injuries resulting from the failure to enforce certain laws. Thus, neither of the other two possible exceptions to the public duty doctrine apply.

²⁶ *Brown*, 126 S.W.3d at 49.

²⁷ *Gardner v. Insura Prop. & Cas. Ins. Co.*, 956 S.W.2d 1, 3 (Tenn. Ct. App. 1997) (dismissing claims against a police officer, where evidence did not show a gross deviation from the standard of care); *Ezell*, 902 S.W.2d at 403 (finding that special duty exception did not apply, where allegations did not establish intentional, malicious, or reckless conduct); *see also Wells*, 2005 Tenn. App. LEXIS, at *23 (affirming trial court’s dismissal of the plaintiff’s claims at the pleading stage, where plaintiff’s complaint did not allege facts sufficient to show that the officer affirmatively undertook to protect the plaintiff).

²⁸ The Defendants cite to materials outside the pleadings, which is inappropriate in connection with a Rule 12(c) motion. The Court’s analysis is therefore limited to the allegations in the pleadings.

standard. The “recklessness” allegations relative to the MBOP are similar and even more tenuous, alleging that the MBOP should have shut down or otherwise disciplined NECC before September 2012.

Essentially, the Defendants argue that it was “reckless” for the FDA and MBOP not to devote more of their attention and resources to pursuing NECC – a single facility in Framingham, Massachusetts – as opposed to the myriad of other entities within their respective jurisdictions. The public duty doctrine already dictates that this conduct does not constitute actionable negligence, let alone recklessness. Indeed, these are precisely the types of allegations that Tennessee has found should *not* be submitted to a jury in light of the public duty doctrine, particularly because a trial on these issues would devolve into an unproductive debate about how limited community resources should have been allocated to protect individual members of the public, an inquiry for which juries and courts are “ill-equipped.”²⁹ This problem is particularly acute relative to the FDA, which exercises regulatory authority over a sprawling array of people and companies across the country, in areas such as food production, medical devices, pharmaceutical drugs, cosmetics, veterinary drugs, radiation-emitting products, biological products, and tobacco. The Defendants cannot plead around the public duty doctrine simply by labeling the government’s purported inaction as “recklessness.”

Notably, the Defendants do not provide a *single case in the history of American jurisprudence* holding a government actor responsible (either directly or via comparative fault) for a plaintiff’s injuries simply because it failed to devote more resources and regulatory oversight to a particular person or company. The Court therefore should not permit this unprecedented theory of fault to proceed.

²⁹ *Eldridge v. City of Trenton*, 1997 Tenn. App. LEXIS 573, at *9-11 (Tenn. Ct. App. Aug. 26, 1997); *Ezell*, 902 S.W.2d at 397-98.

V. The Accusation of “Inaction” by the PSC is Unjustified

The Defendants assert that the PSC should have added the Non-Party Governmental Entities as defendants in this proceeding, and they characterize the PSC’s “failure” to add these entities as “inaction.” These are unfair accusations. The PSC maintains that adding the Non-Party Governmental Entities as defendants would have been futile under the public duty doctrine, not to mention any statutory or sovereign immunity defenses that these entities would have raised. Moreover, unlike the clinical defendants who refuse to accept any measure of responsibility for their prioritization of profits over patient safety, the Plaintiffs do *not* believe that the FDA, the TBOP, the TDOH, the MBOP proximately caused their injuries. Instead, they blame the entities that consciously did business with NECC to support a high-volume epidural steroid injection business at SSC, who violated the patient-specific prescription rule in the interest of profit and convenience over patient safety, and who shirked their basic responsibility to ensure that the medications used in the Plaintiffs’ procedures were safe, effective, and free of contamination. The Defendants continue to seek to foist blame on anyone but themselves, including governmental entities who – unlike the Defendants – had no legal duty to the Plaintiffs. In light of these considerations, the PSC cannot be faulted for refusing to advance claims that it believed were precluded by law and otherwise lack substantive merit.

CONCLUSION

For all of these reasons, the Plaintiffs are entitled to judgment on the pleadings as to the Defendants’ comparative fault defenses relative to the Non-Party Governmental Entities.

Date: January 23, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: January 23, 2017

/s/ Benjamin A. Gastel

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